**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460**

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

April 30, 2018

**MEMORANDUM**

Subject: Efficacy Review for JigSAW,
EPA File. No. 84150-R,
DP Barcode: 445231
E-submission: 24627

From: Sophie Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy RM34/Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: GOJO Industries, Inc.
P.O. Box 991
Akron, OH 44309

**Formulation from the Label:**

| Active Ingredient | % by wt. |
|---|---|
| Ethyl alcohol | 20.0% |
| Other Ingredients | 80.0% |
| Total | 100.0% |

## I. BACKGROUND

**Product Description (as packaged and applied):** To be applied as towelette wipes.

**Submission Type:** New product registration.

**Requested Action:** Registrant is requesting to register a new end use production for use as a food-contact, no rinse sanitizing and disinfecting wipe on hard, non-porous surfaces in commercial and retail markets.

**Documents Submitted for Consideration:**

- A letter to EPA (dated November 28, 2017)
- Application for Pesticide Registration (EPA form 8570-1)
- Confidential Statement of Formula (EPA form 8570-4)
- Certification with Respect to Citation of Data (EPA form 8570-34)
- Data Matrix (EPA Form 8570-35)
- 21 efficacy studies (MRID Nos. 50442610 – 50442630); Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary were included with the study.
- Proposed product label dated November 2017.

## II. USE DIRECTIONS

**SANITIZATION DIRECTIONS**
**[TO] [CLEAN] [and] [SANITIZE] HARD, NONPOROUS NON-FOOD CONTACT SURFACES:**
[Gross] [Heavy] soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wipe surface [to be sanitized] until completely wet. Let stand for 10 seconds. Use enough wipes for treated surface to remain visibly wet for 10 seconds. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 10 seconds contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]
**[TO] [CLEAN] [DEODORIZE] [and] [SANITIZE] HARD, NONPOROUS FOOD CONTACT SURFACES:**
[Gross] [Heavy] soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. [Wash or flush objects with a detergent or cleaner followed by a potable water rinse.] Wipe surface until completely wet. [Rub [wet surface] with clean brush, sponge or cloth.] Treated surfaces must remain wet for 60 seconds/1-minute. [Allow to drain and/or air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 60 second contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]
**[FOR] SANITIZING –or– TO SANITIZE [DISHES¥] [UTENSILS¥] [PLASTIC CUTTTING BOARDS¥]:**
[Gross] [Heavy] soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wash or flush objects with a detergent or cleaner followed by a potable water rinse. Wipe surface until completely wet. Treated surfaces must remain wet for 60 seconds/1 minute. [Allow [equipment] surfaces to [drain] [and/or] air dry [before reuse]]. [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]
**[FOR] SANITIZING –or– TO SANITIZE REFRIGERATORS –and/or– FREEZERS**
[Gross] [Heavy] soil must be removed prior to sanitizing [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Remove food [from refrigerator –and/or– freezer] and allow unit to warm to room temperature. Wipe surfaces until completely wet.
[Rub [wet surface] with clean brush, sponge or cloth.] Treated surfaces must remain wet for 60 seconds/1-minute. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 1-minute contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.] [If desired, wipe with a [lint-free] cloth or paper towel.]
**[FOR] SANITIZING –or– TO SANITIZE GLOVES –and/or– GLOVED HANDS**

To prevent cross contamination from area to area [in] [animal areas] [and] [the packaging and storage areas of food plants], sanitize prewashed (plastic, latex or other synthetic rubber) non-porous gloved hands with this product. Wipe [this product] on the surface of the gloves until completely wet. To sanitize, treated gloves must remain wet for [at least] 10 seconds.

**DISINFECTING DIRECTIONS**

**[TO] [CLEAN] [DEODORIZE] [and] [DISINFECT] HARD, NONPROUS SURFACES [SUCH AS {*select from Hard, Nonporous Use Surfaces*}:**

**-or-**

**[TO] [CLEAN] [,] [AND] DISINFECT [AND DEODORIZE] [HARD, NONPOROUS SURFACES:] [{*select from Hard, Nonporous Use Surfaces*}] [IN 1 STEP] [IN ONE STEP]**

Wipe surface until completely wet. Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below *–or– above –or–* on this label *–or– pathogen list*].

[Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after appropriate contact time has expired.] [No [water] rinse required [even] on food-contact surfaces]]. [Do not rinse [with water]]. [All food contact surfaces such as appliances and kitchen countertops do not need to be rinsed [with water]]. [A water rinse is not required.]

*For heavily soiled surfaces, [a] pre-cleaning [step] [using this product] is required.

**[TO] [CLEAN] [DEODORIZE] [and] [DISINFECT] HARD, NONPROUS FOOD CONTACT SURFACES [SUCH AS {*select from Hard, Nonporous Use Surfaces*}:**

**-or-**

**[TO] [CLEAN] [,] [AND] DISINFECT [AND DEODORIZE] [HARD, NONPOROUS SURFACES:] [{*select from Hard, Nonporous Use Surfaces*}] [IN 1 STEP] [IN ONE STEP]**

Wipe surface until completely wet. Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below *–or– above –or–* on this label *–or– pathogen list*]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after appropriate contact time has expired.] [No [water] rinse required [even] on food-contact surfaces]]. [Do not rinse [with water]]. [All food contact surfaces such as appliances and kitchen countertops do not need to be rinsed [with water]]. [A water rinse is not required.]

*For heavily soiled surfaces, [a] pre-cleaning [step] [using this product] is required.

**TO [CLEAN AND] DISINFECT FOOD PROCESSING PREMISES:**

Wipe surface until completely wet. Treated surfaces must remain wet for [60 seconds/1 minute] [or] [appropriate contact time listed below *–or– above –or–* on this label]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after appropriate contact time has expired.] [No [water] rinse required [even] on food-contact surfaces]]. [Do not rinse [with water]]. [A water rinse is not required.]

*For heavily soiled surfaces, [a] precleaning [step] [using this product] is required.

Food products and packaging materials must be removed or carefully protected prior to using this product.

**TO [CLEAN] [,] [AND] DISINFECT [AND DEODORIZE] REFRIGERATORS –and/or– FREEZERS:**

[Gross] [Heavy] soil must be removed prior to disinfecting [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Remove food [from refrigerator –and/or– freezer] and allow unit to warm to room temperature. Wipe surfaces until completely wet. [Rub [wet surface] with clean brush, sponge or cloth.] Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below *–or– above –or–* on this label *–or–* ***pathogen list***]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.] [If desired, wipe with a [lint-free] cloth or paper towel.]

**TO [CLEAN] [AND] DISINFECT BABY FURNITURE AND HARD NONPOROUS TOYS –OR- HARD, NONPOROUS KID'S TOYS**

Wipe until the surface is completely wet. [Rub [wet surface] with clean brush, sponge or cloth.] To disinfect, treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below *–or– above –or–* on this label *–or–* ***pathogen list***]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.] [If desired, wipe with a [lint-free] cloth or paper towel.]

**TO PRECLEAN INSTRUMENTS PRIOR TO TERMINAL STERILIZATION/HIGH LEVEL DISINFECTION**

Wipe instruments until surfaces are completely wet. Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below *–or– above –or–* on this label *–or–* ***pathogen list***]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after appropriate contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

**TO DISINFECT NON-CRITICAL PRE-CLEANED INSTRUMENTS:**

Instruments must be thoroughly cleaned to remove excess organic debris, rinsed and dried. Wipe all surfaces of instruments with [***product name***] [this product] until completely wet. Treated surfaces must remain wet for [2 minute] –or– [appropriate contact time listed below *–or– above –or–* on this label *–or–* ***pathogen list***]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 2-minute contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

**TO [CLEAN AND] DISINFECT [BARBER] [BEAUTY SALON] [SALON] [SPA] INSTRUMENTS AND TOOLS:**

[Gross] [Heavy] soil must be removed prior to disinfecting [by] [pre-cleaning], [pre-flushing], [and/or] [pre-scraping] [the surface] [or when necessary, pre-soaking]. Wipe all surfaces until completely wet. Treated surfaces must remain wet for [60 Seconds/1 minute] –or– [appropriate contact time listed below –or– above –or– on this label]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

**TO DISINFECT AGAINST THE [COLD] [and/or] [FLU] VIRUS** [‡]

Wipe the surface is completely wet. Let stand for 15 seconds. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 15-second contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

**TO [CLEAN AND] DISINFECT ANIMAL PREMISES –or– QUARTERS –or– KENNELS –and/or– EQUIPMENT**

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stall chutes and other facilities occupied or traversed by animals. Empty all troughs, feeding and watering appliances. Thoroughly clean all surfaces [with this product] and rinse with water. Wipe surfaces until thoroughly wet. Treated surfaces must remain wet for [2 minute] [or] [appropriate contact time listed below *–or– above –or–* on this label]. [Allow to air dry] [or] [if desired] [wipe with a clean, [damp] [cloth or] [paper towel] after 2-minute contact time has expired.] [Do not rinse [with water]]. [No [water] Rinse Required]. [A water rinse is not required.]

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard, Non-porous Surfaces in Hospital or Medical Environments:

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (UDM) (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (GST) (for spray products). Sixty carriers must be tested against each of the three batches of the product at the active ingredient(s) lower certified limit(s) (LCL). For UDM, a mean log density of at least 6.0 (corresponding to a geometric mean density of $1.0 \times 10^6$) and not above 7.0 (corresponding to a geometric mean density of $1.0 \times 10^7$) for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density <6.0 or >7.0 invalidates the test. For GST, a mean log density of at least 5.0 (corresponding to a geometric mean density of $1.0 \times 10^5$) and not above 6.5 (corresponding to a geometric mean density of $3.2 \times 10^6$) for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density <5.0 or >6.5 invalidates the test. To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing (GST) is required. For AOAC Use-Dilution testing (UDM), conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbe. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture

media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results for both UDM and GST methods. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier count to make the test valid should be 1 x $10^4$ CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Sanitizer (For Previously Cleaned, Food Contact Surfaces):
Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 3 samples from each of 3 different product lots at the LCL against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x $10^6$/ml for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The Agency recommends the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) (Ref. 1). The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e.,

porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. For hard, porous surface label claims use unglazed ceramic tile. For hard, nonporous surface label claims use stainless steel carrier or glass slide. Use 5 test carriers and 3 control carriers. Tests should be performed with each of 3 product samples, representing 3 different product lots, tested at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5 x $10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels.*:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.

2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings**:**

| *For an emerging viral pathogen that is a/an…* | *Qualifying criterion* |
|---|---|
| Enveloped virus emerging viral pathogen | At least one large OR one small non-enveloped virus |
| Large, non-enveloped emerging viral pathogen | At least one small, non-enveloped virus |
| Small, non-enveloped emerging viral pathogen | At least two small, non-enveloped viruses with each from a different viral family |

## IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

| **1.** | **MRID** | 50442610 | **Study Completion Date:** | 11/08/17 |
|---|---|---|---|---|
| **Study Objective** | | Hard, non-porous surface disinfectant – additional bacteria | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24008 | | |
| **Test organism(s)** ☒ **1** ☐ **2** ☐ **3** ☐ **4+** | | *Escherichia coli* O157:H7 (ATCC 35150) | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01081017.TOW.5 | | |
| **Application Method** | | Towelette wipes | | |

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|---|---|---|---|---|---|
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots** ☐ 1 ☒ 2 ☐ 3 | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 6% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 10 per batch | | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** | RT: 20°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | | | | |

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| **2.** | **MRID** | 50442611 | **Study Completion Date:** | 11/08/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – additional bacteria | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24145 | | |
| **Test organism(s)** ☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Escherichia coli* O157:H7 (ATCC 35150) | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01092117.TOW | | |
| **Application Method** | | Towelette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots** ☒ 1 ☐ 2 ☐ 3 | 2017-JigSAW-008-2<br>Tested concentration: LCL | | |
| | **Preparation** | Ready-to-use | | |
| **Soil load** | | 6% FBS | | |
| **Carrier type, # per lot** | | Glass slides, 10 per batch | | |
| **Test conditions** | | **Contact time** | 60 sec. | **Temp** | RT: 19°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Reviewer's comment: Batch #2017-JigSAW-008-2 was conducted the second time with same conditions, except the contact time was raised from 53s to 60s. | | |

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| **3.** | **MRID** | 50442612 | **Study Completion Date:** | 10/18/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – additional bacteria | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24007 | | |

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|---|---|---|---|---|---|
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Multi-Drug Resistant (MDR) *Klebsiella pneumoniae* (ATCC 51503) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01081017.TOW.4 | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 6% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 10 per batch | | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** | RT: 20.9°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Reviewer's note: Antibiotic sensitivity testing was not performed under GLP. Results show resistance to multiple drugs. | | | |

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| **4.** | **MRID** | 50442613 | **Study Completion Date:** | | 11/02/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – additional bacteria | | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24095 | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | *Listeria monocytogenes* (ATCC 19117) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01083017.TOW | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 5% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 10 per batch | | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** | RT: 20°C |
| **Neutralizer** | | 20 mL Brain Heart Infusion Broth + 0.14% Lecithin + 1.0% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, | | | | | |

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|---|---|
| control failures, neutralizer, etc.) | |

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| **5.** | **MRID** | 50442614 | **Study Completion Date:** | | 11/03/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – additional bacteria | | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24144 | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01092617.TOW | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 6% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 10 per batch | | | |
| **Test conditions** | | **Contact time** | 80 sec. (10/9/17)<br>90 sec. (10/24/17) | **Temp** | RT: 20 - 21°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Reviewer's note: Antibiotic sensitivity testing was Performed by Accuratus Lab Services using the Kirby Bauer susceptibility assay. Following incubation, the zone of inhibition showing no visible growth was measured. If no zone was present, the size of the disc was reported (6 mm). Table 5 of the study shows the results.<br><br>TEST HISTORY: Testing performed on October 9,2017, resulted in failing efficacy results for Batch 2017-JigSAW-008-1. Per Sponsor's request, the protocol was amended to add additional testing of Batch 2017-JigSAW-008-1 using an exposure time of 90 seconds (See Protocol Amendment). Batch 2017-JigSAW-008-1 was tested on October 24,2017, using an exposure time of 90 seconds, which resulted in valid test results. Testing performed on October 9,2017 and October 24,2017 are both valid and presented in the body of the report.<br><br>Protocol Amendment:<br>Per Sponsor's request, the protocol is amended to add an additional test substance parameter. 2017-JigSAW-008 Batch 2017-JigSAW-008-1 will be tested using a 90 second exposure time. | | | |

| 6. | MRID | 50442615 | Study Completion Date: | 11/02/17 |
|---|---|---|---|---|
| **Study Objective** | | Hard, non-porous surface disinfectant – base organism | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A23932 | | |
| **Test organism(s)**<br>☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Pseudomonas aeruginosa* (ATCC 15442) | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01081017.TOW.1 | | |
| **Application Method** | | Towelette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots**<br>☐ 1 ☐ 2 ☒ 3 | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | |
| | **Preparation** | Ready-to-use | | |
| **Soil load** | | 5% FBS | | |
| **Carrier type, # per lot** | | Glass slides, 60 per batch | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** RT: 21°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | | | |

| 7. | MRID | 50442616 | Study Completion Date: | 11/02/17 |
|---|---|---|---|---|
| **Study Objective** | | Hard, non-porous surface disinfectant – base organism | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A23933 | | |
| **Test organism(s)**<br>☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Salmonella enterica* (ATCC 10708) | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01081017.TOW.2 | | |
| **Application Method** | | Towelette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots**<br>☐ 1 ☐ 2 ☒ 3 | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | |
| | **Preparation** | Ready-to-use | | |
| **Soil load** | | 5% FBS | | |
| **Carrier type, # per lot** | | Glass slides, 60 per batch | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** RT: 20-21°C |

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|---|---|---|---|
| **Neutralizer** | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | TEST HISTORY:<br>Testing on 09/11/17 resulted in growth of a contaminant in one subculture tube for Batch 2017-JigSAW-008-3, causing this batch to exceed the test substance performance criteria. The Neutralization Confirmation Control met acceptance criteria, is valid and presented in the body of the report. Testing of Batch 2017-JigSAW-008-3 was repeated on 09/27/17, resulting in valid results presented in the body of the report. Testing of Batch 2017-JigSAW-008-3 performed on 09/11/17, with the exception of the Neutralization Confirmation Control, is considered invalid and reported in Attachment L Testing was performed in the Same manner on each test date unless otherwise noted.<br><br>Repeated due to contaminant. | | |

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| **8.** | **MRID** | 50442617 | **Study Completion Date:** | | 11/02/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – base organism | | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A23661 | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | *Staphylococcus aureus* (ATCC 6538) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01062617.TOW.1 | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 5% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 60 per batch | | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** | RT: 21°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Failed batches #1 & #3 | | | |

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| **9.** | **MRID** | 50442618 | **Study Completion Date:** | 11/08/17 |

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| **Study Objective** | | Hard, non-porous surface disinfectant – base organism | | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A23797 | | | |
| **Test organism(s)**<br>☒ **1** ☐ **2** ☐ **3** ☐ **4+** | | *Staphylococcus aureus* (ATCC 6538) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01062617.TOW.6 | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots**<br>☐ **1** ☒ **2** ☐ **3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 6% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 60 per batch | | | |
| **Test conditions** | | **Contact time** | 100 sec. | **Temp** | RT: 20°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Failed batch #3 | | | |

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| **10.** | **MRID** | 50442619 | **Study Completion Date:** | | 11/02/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – base organism | | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A23892 | | | |
| **Test organism(s)**<br>☒ **1** ☐ **2** ☐ **3** ☐ **4+** | | *Staphylococcus aureus* (ATCC 6538) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01080417.TOW.2 | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots**<br>☒ **1** ☐ **2** ☐ **3** | 2017-JigSAW-008-3<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 5% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 60 per batch | | | |
| **Test conditions** | | **Contact time** | 110 sec. | **Temp** | RT: 19.8°C |
| **Neutralizer** | | 20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments** | | Result shows one contaminant | | | |

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| (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | |

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| **11.** | **MRID** | 50442620 | **Study Completion Date:** | | 10/10/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – additional bacteria | | | |
| **Study Title** | | Pre-Saturated Towelettes for Hard Surface Disinfection | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24006 | | | |
| **Test organism(s)** ☒ **1** ☐ **2** ☐ **3** ☐ **4+** | | *Streptococcus pyogenes* (ATCC 19615) | | | |
| **Test Method** | | According to modified AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2013) for towelettes, Protocol #GJI01081017.TOW.6 | | | |
| **Application Method** | | Towelette wipes | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | |
| | **Lots** ☐ **1** ☒ **2** ☐ **3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | |
| | **Preparation** | Ready-to-use | | | |
| **Soil load** | | 6% FBS | | | |
| **Carrier type, # per lot** | | Glass slides, 10 per batch | | | |
| **Test conditions** | | **Contact time** | 53 sec. | **Temp** | RT: 20°C |
| **Neutralizer** | | 20 mL Brain Heart Infurion Broth + 0.07% Lecithin + 0.5% Tween 80 | | **Agar Plate Medium** | Tryptic Soy Agar +5% sheep blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | | | | |

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|---|---|---|---|---|
| **12.** | **MRID** | 50442621 | **Study Completion Date:** | 11/21/17 |
| **Study Objective** | | Hard, non-porous surface disinfectant – virus | | |
| **Study Title** | | Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test – Influenza A Virus | | |
| **Testing Lab, Lab Study ID** | | Microbac Laboratories, Inc. ID #512-217 | | |
| **Test Method** | | Protocol ID #512.1.11.09.17 (*copy provided*) | | |
| **Test organism(s)** ☒ **1** ☐ **2** ☐ **3** ☐ **4+** | | Influenza A Virus, A/PR/8/34 (H1N1), Charles River Laboratories | | |
| **Indicator Cell Culture** | | MDCK cells, ATCC CCL-34 | | |
| **Test Medium** | | Minimum Essential Medium (MEM) + 3.0 µg/mL Trypsin | | |
| **Application Method** | | Towlette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots** ☐ **1** ☒ **2** ☐ **3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | |

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|---|---|---|---|---|---|---|---|
| | **Preparation** | Ready-to-use | | | | | |
| **Soil load** | | 5% serum in viral inoculum | | | | | |
| **Carrier type, # per lot** | | Glass carriers | | | | | |
| **Test conditions** | | **Contact time** | 15 sec. | **Temp** | 21°C | **RH** | ~22% |
| **Neutralizer** | | MEM + 1% Fetal Bovine Serum (FBS) + 0.3% Polysorbate 80 + 0.3% Lecithin + 1% HEPES + 1% $NaHCO_3$ | | | | | |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Protocol Amendments:<br>On page 3 of the protocol, the source for MDCK cells is listed as "ATCC CCL-94". This should be "ATCC CCL-34". This amendment serves to correct this typographical error. | | | | | |

| **13.** | **MRID** | 50442622 | **Study Completion Date:** | 11/02/17 |
|---|---|---|---|---|
| **Study Objective** | | Hard, non-porous surface disinfectant – virus | | |
| **Study Title** | | Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24138 | | |
| **Test Method** | | Protocol Number GJI01083017.RSV (*copy provided*) | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Respiratory syncytial virus, ATCC VR-26, Strain Long | | |
| **Indicator Cell Culture** | | Hep-2 (human larynx carcinoma) cells (ATCC CCL-23) | | |
| **Test Medium** | | Minimum Essential Medium (MEM) + 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/ml gentamicin, 100 units/mL penicillin, 2.5 µg/ml amphotericin B and 1.0 mM L-glutamine | | |
| **Application Method** | | Towlette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | |
| | **Preparation** | Ready-to-use | | |
| **Soil load** | | 6% FBS | | |
| **Carrier type, # per lot** | | Glass carriers | | |
| **Test conditions** | | **Contact time** 15 sec. | **Temp** 22°C | **RH** -- |
| **Neutralizer** | | Sephadex Gel Filtration Columns | | |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | | | |

| **14.** | **MRID** | 50442623 | **Study Completion Date:** | 11/02/17 |
|---|---|---|---|---|
| **Study Objective** | | Hard, non-porous surface disinfectant – virus | | |
| **Study Title** | | Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, Project #A24132 | | |
| **Test Method** | | Protocol Number GJI01083017.COR (*copy provided*) | | |

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|---|---|---|---|---|---|---|---|
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Human Coronavirus, ATCC VR-740, Strain 229E | | | | | |
| **Indicator Cell Culture** | | WI-38 (human lung) cells (ATCC CCL-75) | | | | | |
| **Test Medium** | | Minimum Essential Medium (MEM) + 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/ml gentamicin, 100 units/mL penicillin, 2.5 µg/ml amphotericin B | | | | | |
| **Application Method** | | Towlette wipes | | | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | | | |
| | **Preparation** | Ready-to-use | | | | | |
| **Soil load** | | 6% FBS | | | | | |
| **Carrier type, # per lot** | | Glass Petri dishes | | | | | |
| **Test conditions** | | **Contact time** | 15 sec. | **Temp** | 22°C | **RH** | -- |
| **Neutralizer** | | Sephadex Gel Filtration Columns | | | | | |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | | | | | | |

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| **15.** | **MRID** | 50442624 | **Study Completion Date:** | 11/22/17 | | | |
| **Study Objective** | | Hard, non-porous surface disinfectant – virus | | | | | |
| **Study Title** | | Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test – Feline calicivirus (Surrogate for Human Norovirus) | | | | | |
| **Testing Lab, Lab Study ID** | | Microbac Laboratories, Inc. ID #512-213 | | | | | |
| **Test Method** | | Protocol ID #512.1.09.25.17 (*copy provided*) | | | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Feline calicivirus, Strain: F9, ATCC VR-782 | | | | | |
| **Indicator Cell Culture** | | CrFK cells, ATCC CCL-94 | | | | | |
| **Test Medium** | | Minimum Essential Medium (MEM) + 2% Fetal Bovine Serum | | | | | |
| **Application Method** | | Towlette wipes | | | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | | | |
| | **Preparation** | Ready-to-use | | | | | |
| **Soil load** | | 0.05% serum in viral inoculum | | | | | |
| **Carrier type, # per lot** | | Glass carriers | | | | | |
| **Test conditions** | | **Contact time** | 5 min. | **Temp** | 21°C | **RH** | ~35% |
| **Neutralizer** | | MEM + 10% Fetal Bovine Serum (FBS) + 0.3% Polysorbate 80 + 0.3% Lecithin + 1% HEPES + 1% $NaHCO_3$ | | | | | |
| **Reviewer comments**<br>(i.e. protocol deviations and amendments, retesting, | | Protocol Amendments:<br>Protocol pages 3, 6, and 14 state that the virus will have 0% serum. Due to virus availability, and with sponsor approval, the | | | | | |

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| control failures, neutralizer, etc.) | statement should be the virus will have ≤0.05% serum. This amendment serves to change the organic load stated on protocol pages 3, 6, and 14. |

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| **16.** | **MRID** | 50442625 | **Study Completion Date:** | | 11/09/17 | |
| **Study Objective** | | Food Contact Sanitizer | | | | |
| **Study Title** | | Food Contact Sanitizer Test Method for Towelettes | | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, A24175 | | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | *Escherichia coli* (ATCC 11229) | | | | |
| **Test Method** | | Accuratus Lab Services Protocol #GJI01083017.FCST.4 Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, 2013 (*copy provided*)<br>EPA Draft lnterim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes, April 12, 2001 | | | | |
| **Application Method** | | Towelette wipes | | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | | | |
| | **Preparation** | Ready-to-use | | | | |
| **Soil load** | | 6% FBS | | | | |
| **Carrier type, # per lot** | | Sponsor-provided stainless steel carriers, 12” x 12”, 4 per lot, 4 sq. ft. total | | | | |
| **Test conditions** | | **Contact time** | 23 sec. | **Temp** | 20°C | **RH** -- |
| **Neutralizer** | | 1 carrier in 500 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80) | | **Subculture Agar medium** | | Tryptic Soy Agar + 5% Sheep’s Blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | | | | | |

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| **17.** | **MRID** | 50442626 | **Study Completion Date:** | 11/09/17 |
| **Study Objective** | | Food Contact Sanitizer | | |
| **Study Title** | | Food Contact Sanitizer Test Method for Towelettes | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, A24069 | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | *Escherichia coli* (ATCC 11229) | | |
| **Test Method** | | Accuratus Lab Services Protocol #GJI01083017.FCST.4 Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, 2013 (*copy provided*) | | |

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|---|---|---|---|---|---|---|
| | | EPA Draft lnterim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes, April 12, 2001 | | | | |
| **Application Method** | | Towelette wipes | | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | | |
| | **Lots** ☐ **1** ☐ **2** ☒ **3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | | | |
| | **Preparation** | Ready-to-use | | | | |
| **Soil load** | | 6% FBS | | | | |
| **Carrier type, # per lot** | | Sponsor-provided rough (textured) plastic carriers, 12” x 12”, 4 per lot, 4 sq. ft. total | | | | |
| **Test conditions** | | **Contact time** | 23 sec. | **Temp** | 20°C | **RH** -- |
| **Neutralizer** | | 1 carrier in 500 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80) | | **Subculture Agar medium** | | Tryptic Soy Agar + 5% Sheep’s Blood |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Protocol deviation: For the preparation of test organism, the protocol states that Nutrient Agar A (NAA) and Nutrient Agar B (NAB) will be used as the growth media. Due to NAB not being available on the weekend for subculture, NAA and Tryptic Soy + 5% Sheep Blood were used. Acceptance of this results in the deviation. Since there was enough growth on the media to prepare the planned spectrophotometer reading, this deviation has no impact on the testing. | | | | |

| **18.** | **MRID** | 50442627 | **Study Completion Date:** | 11/20/17 |
|---|---|---|---|---|
| **Study Objective** | | Food Contact Sanitizer | | |
| **Study Title** | | Food Contact Sanitizer Test Method for Towelettes | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, A24117 | | |
| **Test organism(s)** ☒ **1** ☐ **2** ☐ **3** ☐ **4+** | | *Staphylococcus aureus* (ATCC 6538) | | |
| **Test Method** | | Accuratus Lab Services Protocol #GJI01083017.FCST.2 Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, 2013 (*copy provided*)<br>EPA Draft lnterim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes, April 12, 2001 | | |
| **Application Method** | | Towelette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots** ☐ **1** ☐ **2** ☒ **3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | |
| | **Preparation** | Ready-to-use | | |

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|---|---|---|---|---|---|---|
| **Soil load** | 6% FBS | | | | | |
| **Carrier type, # per lot** | Sponsor-provided stainless steel carriers, 12” x 12”, 4 per lot, 4 sq. ft. total | | | | | |
| **Test conditions** | **Contact time** | 23 sec. | **Temp** | 20°C | **RH** | -- |
| **Neutralizer** | 1 carrier in 500 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80) | | **Subculture Agar medium** | | Tryptic Soy Agar + 5% Sheep’s Blood | |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | Test History: Testing performed 10/3/17 resulted in carrier population control failure and invalid data for the control and test. Testing was repeated on 11/6/17 and resulted in valid data which is contained throughout the body of the report. Invalid data can be found in Attachment I.<br><br>Protocol Amendments:<br>1. Per Sponsor’s request and due to carrier population control failure, modification 1 of the protocol is amended to target an organism population of ~7.9 x $10^9$ CFU/mL. At 620 nm, a 0.75 absorbance after a 1:4 dilution should target this population, however alternate absorbance values may be targeted to meet the carrier population acceptance criteria.<br>2. Per Sponsor’s request, the protocol is amended to update the wiping procedure. When wiping each carrier for the second time, the carriers are to be wiped left to right instead of up and down. | | | | | |

| **19.** | **MRID** | 50442628 | **Study Completion Date:** | 11/09/17 |
|---|---|---|---|---|
| **Study Objective** | | Food Contact Sanitizer | | |
| **Study Title** | | Food Contact Sanitizer Test Method for Towelettes | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, A24039 | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | *Staphylococcus aureus* (ATCC 6538) | | |
| **Test Method** | | Accuratus Lab Services Protocol #GJI01083017.FCST.1 Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, 2013 (*copy provided*)<br>EPA Draft lnterim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes, April 12, 2001 | | |
| **Application Method** | | Towelette wipes | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | |
| | **Preparation** | Ready-to-use | | |
| **Soil load** | | 6% FBS | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Carrier type, # per lot** | Sponsor-provided rough (textured) plastic carriers, 12” x 12”, 4 per lot, 4 sq. ft. total | | | | | |
| **Test conditions** | **Contact time** | 23 sec. | **Temp** | 20°C | **RH** | -- |
| **Neutralizer** | 1 carrier in 500 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80) | | **Subculture Agar medium** | | Tryptic Soy Agar + 5% Sheep’s Blood | |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | Batch #2017-JigSAW-008-3 passed, and Batches # 2017-JigSAW-008-1 & 2017-JigSAW-008-2 did not, according to the Study Conclusion.<br><br>Test repeated, refer to study #20, MRID 50442629 | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **20.** | **MRID** | 50442629 | **Study Completion Date:** | | 11/21/17 | |
| **Study Objective** | | Food Contact Sanitizer | | | | |
| **Study Title** | | Food Contact Sanitizer Test Method for Towelettes | | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, A24189 | | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | *Staphylococcus aureus* (ATCC 6538) | | | | |
| **Test Method** | | Accuratus Lab Services Protocol #GJI01092817.FCST Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, 2013 (*copy provided*)<br>EPA Draft lnterim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes, April 12, 2001 | | | | |
| **Application Method** | | Towelette wipes | | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>Tested concentration: LCL | | | | |
| | **Preparation** | Ready-to-use | | | | |
| **Soil load** | | 5% FBS on 10/16/17 and 6% FBS on 11/6/17 | | | | |
| **Carrier type, # per lot** | | Sponsor-provided rough (textured) plastic carriers, 12” x 12”, 4 per lot, 4 sq. ft. total | | | | |
| **Test conditions** | | **Contact time** | 23 sec. (10/16/17)<br>30 sec. (11/6/17 | **Temp** | 20°C | **RH** | -- |
| **Neutralizer** | | 1 carrier in 500 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80) | | **Subculture Agar medium** | | Tryptic Soy Agar + 5% Sheep’s Blood | |
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Both batches were repeated with same contact time initially. Batch #2017-JigSAW-008-1 was repeated with a higher contact time and higher soil load with a different wiping procedure.<br><br>Test History: Testing performed 10/16/17 resulted in test failure for Batch 2017-JigSAW-008-1. Per Sponsor's request, | | | | | |

| | |
|---|---|
| | additional testing was performed per protocol Amendment 1. All data is valid and is contained in the body of the report.<br><br>Per Sponsor's request, the protocol is amended to allow additional testing of LOT 2017-JigSAW-008-1 with the following changes:<br>a. Exposure time is 30 seconds.<br>b. 6% organic soil load.<br>c. When wiping each carrier for the second time, the procedure will be performed wiping left to right instead of up and down.<br>d. An appropriate absorbance value will be targeted to meet the carrier population acceptance criteria. |

| | | | | | | |
|---|---|---|---|---|---|---|
| **21.** | **MRID** | 50442630 | **Study Completion Date:** | | 11/07/17 | |
| **Study Objective** | | Non-Food Contact Sanitizer | | | | |
| **Study Title** | | Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Product Application) | | | | |
| **Testing Lab, Lab Study ID** | | Accuratus Lab Services, A24127 | | | | |
| **Test organism(s)**<br>**☐ 1 ☒ 2 ☐ 3 ☐ 4+** | | *Klebsiella pneumoniae* (ATCC 4352)<br>*Staphylococcus aureus* (ATCC 6538) | | | | |
| **Test Method** | | Accuratus Lab Services Protocol #GJI01091417.NFS<br>Modified ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, E1153-14<br>Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, 2013<br>ASTM Standard Practice for Evaluation of Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection, E2362-15<br>(*copy provided*) | | | | |
| **Application Method** | | Towelette wipes | | | | |
| **Test Substance Preparation** | **Name/ID** | 2017-JigSAW-008 | | | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | 2017-JigSAW-008-1<br>2017-JigSAW-008-2<br>2017-JigSAW-008-3<br>Tested concentration: LCL | | | | |
| | **Preparation** | Ready-to-use | | | | |
| **Soil load** | | 6% FBS | | | | |
| **Carrier type, # per lot** | | Glass 1" x 1" carriers, 5 carriers | | | | |
| **Test conditions** | | **Contact time** | 10 sec. | **Temp** | 20°C | **RH** | -- |
| **Neutralizer** | | 1 carrier in 20 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80) | | **Subculture Agar medium** | | Tryptic Soy Agar + 5% Sheep's Blood | |

| | |
|---|---|
| **Reviewer comments** (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | Each inoculated was treated with the towelette by passing over the carrier surface back and forth twice for a total of 4 passes using staggered interval. |

## V. RESULTS

| Bactericidal Activity | | | | | | |
|---|---|---|---|---|---|---|
| **MRID No.** | **Contact Time** | **Organism** | **No. Carriers Exhibiting Growth/ Total Carriers** | | | **Average Carrier Population Control Log (CFU/Carrier)** |
| | | | **2017-JigSAW-008-1** | **2017-JigSAW-008-2** | **2017-JigSAW-008-3** | |
| 50442610 | 53 sec. | *Escherichia coli* O157:H7 (ATCC 35150) | 0/10 | 1/10 | -- | 6.00 |
| 50442611 | 60 sec. | | -- | 0/10 | -- | 4.82 |
| 50442612 | 53 sec. | MDR *Klebsiella pneumoniae* (ATCC 51503) | 0/10 | 0/10 | -- | 6.48 |
| 50442613 | 53 sec. | *Listeria monocytogenes* (ATCC 19117) | 0/10 | 0/10 | -- | 6.62 |
| 50442614 | 80 sec. | *Staphylococcus aureus* MRSA (ATCC 33592) | 10/9/17 | | | |
| | | | 1/10 | 0/10 | -- | 4.38 |
| | 90 sec. | | 10/24/17 | | | |
| | | | 0/10 | -- | -- | 4.48 |
| 50442615 | 53 sec. | *Pseudomonas aeruginosa* (15442) | 0/60 | 0/60 | 0/60 | 5.73 |
| 50442616 | 53 sec. | *Salmonella enterica* (ATCC 10708) | 9/11/17 | | | |
| | | | 0/60 | 0/60 | 1/60[1] | 4.55 |
| | | | 9/27/17 | | | |
| | | | -- | -- | 0/60[2] | 5.10 |
| 50442617 | 53 sec. | *Staphylococcus aureus* (ATCC 6538) | 5/60 | 1/60 | 3/60 | 5.82 |
| 50442618 | 100 sec. | | 1/60 | -- | 2/60 | 5.79 |
| 50442619 | 110 sec. | | -- | -- | 0/60[3] | 5.82 |
| 50442620 | 53 sec. | *Streptococcus pyogenes* (ATCC 19615) | 0/10 | 0/10 | -- | 6.94 |

[1] Report considered as invalid data. Two carriers showing growth, one of which was confirmed as contaminant based on Gram stain and biochemical assay information.
[2] Test was repeated due to contaminant.
[3] Report considered as valid data. One carrier showing growth, which was confirmed as a contaminant based on Gram stain and biochemical assay information.

| Virucidal Activity | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **MRID No.** | **Contact Time** | **Organism** | **Results** | | | | | **Plate Recovery Control** |
| | | | | **Batch# 2017-JigSAW-008-1** | | **Batch# 2017-JigSAW-008-2** | | |
| | | | **Description** | **Rep. 1** | **Rep. 2** | **Rep. 1** | **Rep. 2** | |
| 50442621 | 15 sec. | Influenza A Virus, A/PR/8/34 (H1N1), Charles River Laboratories | $10^{-2}$ to $10^{-7}$ dilutions | Complete Inactivation | -- | Complete Inactivation | -- | ($Log_{10}$ $TCID_{50}$/mL) 4.75 |
| | | | $Log_{10}$ $TCID_{50}$/mL | ≤1.50 | -- | ≤1.50 | -- | |
| | | | $Log_{10}$ $TCID_{50}$/carrier (0.2mL) | ≤0.80 | -- | ≤0.80 | -- | |
| | | | $Log_{10}$ Reduction | ≥3.25 | -- | ≥3.25 | -- | |
| 50442622 | | Respiratory syncytial virus, ATCC VR-26, Strain Long | $10^{-2}$ to $10^{-6}$ dilutions | Complete Inactivation | -- | Complete Inactivation | -- | ($TCID_{50}$/100µL) $10^{4.50}$ |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | -- | $\leq 10^{1.50}$ | -- | |
| | | | $Log_{10}$ Reduction | ≥3.00 | -- | ≥3.00 | -- | |
| 50442623 | | Human Coronavirus, ATCC VR-740, Strain 229E | $10^{-1}$ to $10^{-6}$ dilutions | Complete Inactivation | -- | Complete Inactivation | -- | ($TCID_{50}$/100µL) $10^{4.50}$ |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | -- | $\leq 10^{0.50}$ | -- | |
| | | | $Log_{10}$ Reduction | ≥4.00 | -- | ≥4.00 | -- | |
| 50442624 | 5 min. | Feline calicivirus, Strain: F9, ATCC VR-782 | $10^{-2}$ to $10^{-7}$ dilutions | Complete Inactivation | Complete Inactivation | Complete Inactivation | Complete Inactivation | ($Log_{10}$ $TCID_{50}$/carrier) 4.87 |
| | | | $Log_{10}$ $TCID_{50}$/mL | ≤2.80 | ≤2.80 | ≤2.80 | ≤2.80 | |
| | | | $Log_{10}$ $TCID_{50}$/carrier (0.2mL) | ≤2.10 | ≤2.10 | ≤2.10 | ≤2.10 | |
| | | | $Log_{10}$ Reduction | ≥2.77 | ≥2.77 | ≥2.77 | ≥2.77 | |

## Hard, Non-Porous Food Contact Surface Sanitizer

| **Contact Time** | **MRID No.** | **Carrier Type** | **Organism** | **Results** | | | **Numbers Control Average CFU/mL ($Log_{10}$)** |
|---|---|---|---|---|---|---|---|
| | | | | **Batch No.** | **Average CFU/mL ($Log_{10}$)** | **$Log_{10}$ Reduction** | |
| 23 sec. | 50442625 | Stainless steel surface | *Escherichia coli* (ATCC 11229) | 2017-JigSAW-008-1 | $<1.70 \times 10^2$ (<2.23) | >99.9999% (>6.62) | $7.10 \times 10^8$ (8.85) |
| | | | | 2017-JigSAW-008-2 | $<6.61 \times 10^1$ (<1.82) | >99.99999% (>7.03) | |
| | | | | 2017-JigSAW-008-3 | $<9.33 \times 10^2$ (<2.97) | >99.999% (>5.88) | |
| | 50442626 | Rough plastic surface | | 2017-JigSAW-008-1 | $<2.19 \times 10^2$ (<2.34) | >99.9999% (>6.86) | $1.6 \times 10^9$ (9.20) |
| | | | | 2017-JigSAW-008-2 | $<1.02 \times 10^3$ (<3.01) | >99.9999% (>6.19) | |
| | | | | 2017-JigSAW-008-3 | $<3.39 \times 10^1$ (<1.53) | >99.99999% (>7.67) | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 50442627 | Stainless steel surface | *Staphylococcus aureus* (ATCC 6538) | 2017-JigSAW-008-1 | $2.69 \times 10^3$ (3.43) | >99.999% (5.83) | $1.8 \times 10^9$ (9.26) |
| | | | | 2017-JigSAW-008-2 | $5.13 \times 10^3$ (3.71) | >99.999% (5.55) | |
| | | | | 2017-JigSAW-008-3 | $2.14 \times 10^3$ (3.33) | >99.999% (5.93) | |
| | 50442628 | Rough plastic surface | | 2017-JigSAW-008-1 | $3.31 \times 10^3$ (3.52) | >99.99% (4.88) | $2.5 \times 10^8$ (8.40) |
| | | | | 2017-JigSAW-008-2 | $<7.94 \times 10^3$ (<3.90) | >99.99% (>4.50) | |
| | | | | 2017-JigSAW-008-3 | $<4.47 \times 10^2$ (<2.65) | >99.999% (>5.75) | |
| 23 sec. | 50442629[4] | | | 10/16/17 | | | |
| | | | | 2017-JigSAW-008-1 | $<5.37 \times 10^3$ (<3.73) | >99.994% (>4.22) | $8.90 \times 10^7$ (7.95) |
| | | | | 2017-JigSAW-008-2 | $<2.57 \times 10^2$ (<2.41) | >99.999% (>5.54) | |
| 30 sec. | | | | 11/6/17 | | | |
| | | | | 2017-JigSAW-008-1 | $<5.50 \times 10^2$ (<2.74) | >99.999% (>5.14) | $7.55 \times 10^7$ (7.88) |

**Hard, Non-Porous, Non-Food Contact Surface Sanitizer**

| Contact Time | MRID No. | Organism | Results | | | Carrier Population Average CFU/carrier (Average $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch No. | Average CFU/carrier | Percent Reduction | |
| 10 sec. | 50442630 | *Staphylococcus aureus* (ATCC 6538) | 2017-JigSAW-008-1 | $3.72 \times 10^2$ (2.57) | >99.9% | $2.57 \times 10^6$ (6.41) |
| | | | 2017-JigSAW-008-2 | $2.63 \times 10^2$ (2.42) | >99.9% | |
| | | | 2017-JigSAW-008-3 | $3.63 \times 10^2$ (2.56) | >99.9% | |
| | | *Klebsiella pneumoniae* (ATCC 4352) | 2017-JigSAW-008-1 | $<2.00 \times 10^1$ (<1.30) | >99.9% | $2.69 \times 10^7$ (7.43) |

[4] Batches were repeated because of failure. See Reviewer's comment in study #19.

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | 2017-JigSAW-008-2 | <5.01 x $10^1$ (<1.70) | >99.9% | |
| | | | 2017-JigSAW-008-3 | <2.75 x $10^1$ <1.44 | >99.9% | |

## VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a disinfectant towelette with bactericidal activity against the following microorganisms for the indicated contact times below on hard, non-porous surfaces in the presence of at least 5% organic soil load.

| MRID | Organism | Contact Time |
|---|---|---|
| 50442610 (1 batch) | *Escherichia coli O157:H7* (ATCC 35150) | 53 sec. |
| 50442611 (1 batch) | *Escherichia coli O157:H7* (ATCC 35150) | 60 sec. |
| 50442612 | ǂMDR *Klebsiella pneumoniae* (ATCC 51503) | 53 sec. |
| 50442613 | *Listeria monocytogenes* (ATCC 19117) | 53 sec. |
| 50442614 | ¥*Staphylococcus aureus* MRSA (ATCC 33592) | 90 sec. |
| 50442615 | *Pseudomonas aeruginosa* (15442) | 53 sec. |
| 50442616 | *Salmonella enterica* (ATCC 10708) | 53 sec. |
| 50442617 (1 batch) | *Staphylococcus aureus* (ATCC 6538) | 53 sec. |
| 50442618 (1 batch) | *Staphylococcus aureus* (ATCC 6538) | 100 sec. |
| 50442619 (1 batch) | *Staphylococcus aureus* (ATCC 6538) | 110 sec. |
| 50442620 | *Streptococcus pyogenes* (ATCC 19615) | 53 sec. |

ǂThe test organism antibiotic resistance profile showed resistance to multiple drugs, including Ampicillin, Ambicillin/Sulbactam, Cefazolin, Cefepime, Ceftazidime, Ceftriaxone, Gentamicin, Piperacillin/Tazo, and Meropenem.
¥The test organism antibiotic resistance profiles showed resistance to Oxacillin antibiotic disks.

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a disinfectant towelette with virucidal activity against the following microorganisms for 15 sec. contact time on hard, non-porous surfaces in the presence of at least 5% organic soil load:

| MRID | Organism |
|---|---|
| 50442621 | Influenza A Virus, A/PR/8/34 (H1N1), Charles River Laboratories |
| 50442622 | Respiratory syncytial virus, ATCC VR-26, Strain Long |
| 50442623 | Human Coronavirus, ATCC VR-740, Strain 229E |

Recoverable virus titers of at least $10^4$ were achieved. Complete inactivation (no growth) was achieved in the dilutions indicated. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

3. The submitted efficacy data **does not support** the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a disinfectant towelette with virucidal activity against the following microorganisms for 5 min. contact time on hard, non-porous surfaces in the presence of 0.05% organic soil load:

| MRID | Organism |
|---|---|
| 50442624 | Feline calicivirus, Strain: F9, ATCC VR-782 |

Recoverable virus titers of at least $10^4$ were achieved. Complete inactivation (no growth) was achieved in the dilutions indicated. At least a 3-log reduction in titer was **not** demonstrated beyond the cytotoxic level.

4. The submitted efficacy data **support** the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a food contact surface sanitizer towelette against the following microorganisms for the indicated contact times on hard, non-porous, food contact surfaces in the presence of at least 5% organic soil load:

| MRID | Organism |
|---|---|
| 50442625 | *Escherichia coli* (ATCC 11229), stainless steel, 23 sec. |
| 50442626 | *Escherichia coli* (ATCC 11229), rough plastic, 23 sec. |
| 50442627 | *Staphylococcus aureus* (ATCC 6538), stainless steel, 23 sec. |
| 50442628 (1 batch) | *Staphylococcus aureus* (ATCC 6538), rough plastic, 23 sec. |
| 50442629 (2 batches) | *Staphylococcus aureus* (ATCC 6538), rough plastic, 23 sec. & 30 sec. |

At least a 5-log reduction in the numbers of the organisms for the required number of product lots were demonstrated compared to the initial number control results within 30 seconds. Purity control was reported as pure. Sterility controls were reported as no growth. Neutralization confirmation control results were reported as passing.

5. The submitted efficacy data **support** the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a non-food contact surface sanitizer towelette against the following microorganisms for a 10-second contact time on hard, non-porous, non-food contact surfaces in the presence of at least 5% organic soil load:

| MRID | Organism |
|---|---|
| 50442630 | *Klebsiella pneumoniae* (ATCC 4352) |
| | *Staphylococcus aureus* (ATCC 6538) |

At least a 3-$\log_{10}$ reduction in the numbers of both organisms for the required number of product lots were demonstrated compared to the initial number control results within 5 minutes. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Sterility controls did not show growth.

## VII. LABEL RECOMMENDATIONS (for label version Nov. 2017)

1. The proposed label claims are acceptable regarding the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a disinfectant towelette with bactericidal activity against the following organisms for use on hard, non-porous surfaces at the indicated contact time or at 2 minutes.

| | |
|---|---|
| *Escherichia coli* O157:H7 (ATCC 35150) | 60 sec. |
| MDR *Klebsiella pneumoniae* (ATCC 51503) | 60 sec. |
| *Listeria monocytogenes* (ATCC 19117) | 60 sec. |
| *Staphylococcus aureus* MRSA (ATCC 33592) | 80 sec. |
| *Pseudomonas aeruginosa* (15442) | 60 sec. |
| *Salmonella enterica* (ATCC 10708) | 60 sec. |
| *Staphylococcus aureus* (ATCC 6538) | 110 sec. |

*Streptococcus pyogenes* (ATCC 19615) 60 sec.

These claims **are supported** by the applicant's data.

2. The proposed label claims are acceptable regarding the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a disinfectant towelette with virucidal activity against the following organisms for use on hard, non-porous surfaces at 15 seconds.

   Influenza A Virus (H1N1)
   Respiratory syncytial virus [RSV], Strain Long
   Human Coronavirus, Strain 229E

   These claims **are supported** by the applicant's data.

3. The proposed label claim is not acceptable regarding the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a disinfectant towelette with virucidal activity against the following organism for use on hard, non-porous surfaces at 5 minutes.

   Feline calicivirus, Strain: F9, ATCC VR-782

   This claim **is not supported** by the applicant's data. Please remove this organism from the proposed label.

4. The proposed label claim is not acceptable regarding the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a food contact surface sanitizer towelette against the following organism for use on hard, non-porous, food contact surfaces at 60 seconds.

   *Escherichia coli* (ATCC 11229)
   *Staphylococcus aureus* (ATCC 6538)

   These claims **are supported** by the applicant's data.

5. The proposed label claim is not acceptable regarding the use of the product, JigSAW, EPA Reg. File No. 84150-R, as a non-food contact surface sanitizer towelette against the following organism for use on hard, non-porous, non-food contact surfaces at 10 seconds.

   *Klebsiella pneumoniae* (ATCC 4352)
   *Staphylococcus aureus* (ATCC 6538)

   These claims **are supported** by the applicant's data.

6. Registrant should note that food contact sanitizer products formulated and tested as towelettes are intended to be used to sanitize hard, non-porous surfaces which may come into contact with food, including but not limited to hard, non-porous tables, countertops (stainless steel, laminated, sealed ceramic), stove tops, and interior and exterior surfaces of microwaves and refrigerators. The list of surfaces supported by this use does not include utensils, glasses, food containers, dishes, cutting boards and cutting blocks, drain boards and food processing equipment.

   For this reason, please remove the use directions “[For] Sanitizing -or- to sanitize [dishes] [utensils] [plastic cutting boards]” on page 5. Additionally, please remove any claims that the product can be used to sanitize utensils, glasses, food containers, dishes, etc.

The label should include a disclaimer that the product cannot be used to sanitize specific food contact surfaces, such as utensils, glasses, food containers, dishes, cutting boards and cutting blocks, drain boards, and food processing equipment.

7. Under SANITIZATION DIRECTIONS and throughout the label, remove/revise the following:
    a. The instruction to "Rub [wet surface] with clean brush, sponge or cloth" cannot be used before the contact time is achieved. This phrase should be added after the contact time is mentioned. Surface must remain visibly wet for the duration of the contact time.
    b. Replace the terms "heavy soil" with "visible soil". For example, the directions that "[Heavy] soil must be removed prior to sanitizing" should be revised to "Visible soil must be removed prior to sanitizing…". The phrase "visible soil" should not be used with brackets.

8. Under DISINFECTING DIRECTIONS, please remove/revise the following:
    a. For every use-direction, the directions to remove or pre-clean visible soil on surfaces must be added before product application. For example, the instruction to "thoroughly clean visible soil from surface before disinfection" should be added before the instruction to "wipe surface until completely wet."
    b. Replace the terms "heavy soil" with "visible soil". Refer to label comment #7b.
    c. Remove the instruction to "Rub [wet surface] with clean brush, sponge or cloth" from all use directions. Refer to label comment #7a.
    d. Clarify the use-directions for food processing premises. Product cannot be used on food processing equipment.
    e. Under "TO DISINFECT AGAINST THE [COLD] [AND/OR] [FLU] VIRUS", the instruction to "Let stand for 15 seconds" should be revised to "Treated surfaces must remain wet for 15 seconds".

9. On page 9 or the proposed label, please remove Feline Calicivirus and Human Norovirus/Norwalk-like virus claims.

10. On page 10 of the proposed label, remove/revise the following:
    a. Remove the claim "All-in-one" as this claim is false and misleading.
    b. Remove the terms "quick", "easy", "fast", and "convenient" from this page and throughout the label, unless they are used to describe non-public health uses, such as cleaning, deodorizing, degreaser, etc., or unless they are specific to non-food contact sanitization claims. Claims for "quick," "easy," and "fast" are limited to labeled contact times of 30 seconds or less.
    c. The claim "This product is effective in the presence of 5% organic soil" should be qualified. The product is an effective disinfectant/sanitizer against the tested organisms.
    d. Whenever the claims for "all around" the house, kitchen, bathroom, etc. are mentioned, please qualify to indicate "hard, non-porous surfaces".

11. On page 11 of the proposed label, remove/revise the following:
    a. The claim "[Tough], [Strong], [Durable] wipe to cover more surface area" is ambiguous and should either be removed or clarified further. Comparative statements are limited to within a company's own products.
    b. Remove brackets from "hard non-porous surfaces" in the claim "(Effectively) works on (many) (most) (a wide range of) (household) (kitchen) (bathroom) (workplace) (office) (hard non-porous surfaces)".

12. On page 12 of the proposed label, remove/revise the following:
    a. Remove "disinfecting" and "sanitizing" from the claim "(Great) (excellent) (for) (quick clean ups) [touch up] [disinfecting] [sanitizing] [cleaning]". This claim implies heightened efficacy when used with the words "great" and "excellent".

b. Whenever the claims to disinfect or sanitize "all around" the house, kitchen, bathroom, etc. are mentioned, please qualify to indicate "hard, non-porous surfaces". Please qualify this claim throughout the label.
c. Remove "disinfecting" and "sanitizing" from the claim "Powerful [disinfecting] [sanitizing] [cleaning]-and/or- degreasing action -or- formula". The term "powerful" cannot be used to describe disinfection or sanitization as it implies heightened efficacy.
d. Remove the claim for "germs" from this page and throughout the label. Appropriate testing was not conducted to make this claim. Please see the following for criteria to make claims for "germs:" https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels.
e. Remove "Wipe and walk away". The contact time(s) must be monitored after product application to ensure that the surface remains wet. Similarly, remove "Wipe & go".
f. The claim "Targets the places where … [bacteria] hide" should be revised to "Targets the hard, non-porous places where bacteria hide".

13. On page 13 of the proposed label, remove/revise the following:
    a. The claim "For [light] -or- touch-up – daily -or- quick [disinfecting] [sanitizing] [cleaning] -or- [disinfects] [sanitizes] [clean-ups] [in one convenient step]" should specify at the end using the phrase "when the use-directions for disinfection and sanitization are followed."
    b. Remove "disinfect" and "sanitize" from the claim "[Disinfect] [Sanitize] [Clean] with just a wipe -or- touch". To disinfect and sanitize, the product has to be applied and potentially reapplied to keep the surface wet for the duration of the contact time. Therefore, this claim is misleading.
    c. "Remove "disinfects" and "sanitizes" from the claim "Wipes away -and/or- powers through -and/or- attacks -and/or- [even] [disinfects] [sanitizes] [cleans] [tough] [stubborn] [baked-on] [dried-on] [kitchen] grease -and/or- grime -and/or- dirt -and/or- soap scum -and/or- [everyday] [bathroom] [kitchen] messes -and/or- build-up".
    d. Specify hard, non-porous surfaces in the claim "Specially formulated to [disinfect] [sanitize] [clean] [a variety of surfaces] [throughout-or- all over -or- around] the house -or- kitchen and bathroom."
    e. Remove "disinfectant" and "sanitizer" from the claim "Powerful (fast acting) (effective) (degreaser) [disinfectant] [sanitizer] [cleaner]."
    f. Remove "disinfects" and "sanitizes" from the claim "(Powers through) [disinfects] [sanitizes] [cleans] (traps) (messes) (soap scum) (soils) (stains)."
    g. Remove "Maximum [disinfecting] [sanitizing]" from the claim "Maximum [disinfecting] [sanitizing] [cleaning], Minimum Effort."
    h. The product cannot be used to disinfect and sanitize spills and messes. Remove every claim on this page and throughout the label that implies this. For example, remove "Multi-Surface [disinfectant] [sanitizer] [cleaner] for Spills and Messes." Spills, messes, grease, soap scum, etc. may be cleaned up but not disinfected or sanitized.

14. On page 14 of the proposed label, revise/remove the following:
    a. Remove "disinfecting" and "sanitizing" from "Helps you finish [disinfecting] [sanitizing] [cleaning] (fast) (quickly)."
    b. Specify hard, non-porous surfaces in the claim "[Safe] [Gentle] on -or- [Disinfects] [Sanitizes] [Cleans] A [Variety Of] [Multiple] Surfaces."
    c. The claim "This patent pending product is a [one-step] [1 step] cleaner, deodorizer, sanitizer, disinfectant and virucide† that is effective against a broad spectrum of pathogens (complete kill in the presence of 5% organic soil)" should be qualified by adding the phrase "when use-directions for disinfection and sanitization are followed." Similarly, the claim "[One Step] [1 Step] [No pre-cleaning required] [cleaner] [disinfectant] [deodorizer] [sanitizer] [degreaser] [virucide†]" should be properly qualified.
    d. The claim "This product is a no-rinse disinfectant cleaner that disinfects, cleans and deodorizes in just [1] [one] labor saving step" should be qualified by adding the phrase

"when use-directions for disinfection are followed." Similarly, the claim "Disinfects and Deodorizes Food Contact Surfaces in One Step" should be properly qualified.

e. Remove the claim "This patent pending product kills norovirus including murine norovirus and Norwalk-like virus (Feline calicivirus). [Surfaces must be pre-cleaned]."
f. Remove "Disinfects food prep surfaces" or further clarify these surfaces.
g. Qualify the claim "Disinfects and Deodorizes Food Contact Surfaces in One Step" by adding the phrase "when use-directions for disinfection are followed."
h. Qualify the claim "Helps reduce the risk of cross-contamination" by adding "on treated surfaces."
i. Revise the claim "Helps prevent cross-contamination [on treated surfaces]" with "helps reduce cross-contamination on treated surfaces". The brackets should be removed.
j. Qualify all claims for viruses (e.g. virucide or virucidal) throughout the label.
k. Revise the claim "Kills 99.9[9][9]% of bacteria [on surfaces]" with "Kills 99.9% of bacteria on hard, non-porous surfaces", unless the claim is qualified to reference and specify only for use as a food contact surface sanitizer.
l. Remove "on moist surfaces" from the claim "This product inhibits bacterial growth on moist surfaces and deodorizes by killing microorganisms that cause offensive odors." Efficacy data did not substantiate this claim.
m. The claim "[Kills] [eliminates] [destroys] [removes] [bacteria [and/or] viruses] on commonly touched surfaces that can be transfer points [such as doorknobs, telephones, keyboards, and light switches]" should be revised with "[Kills] [eliminates] [destroys] [removes] [bacteria [and/or] viruses] on commonly touched <u>hard, non-porous</u> surfaces that can be transfer points [such as doorknobs, telephones, keyboards, and light switches]".

15. On page 15 of the proposed label, remove/revise the following:
    a. Remove the claim "Kills common household bacteria". The agency does not have criteria for "common household bacteria".
    b. Revise the claim "To [clean] [,] [disinfect [,] [and] [sanitize] the [surfaces] [things] you touch" with "To [clean] [,] [disinfect [,] [and] [sanitize] the <u>hard, non-porous</u> [surfaces] [things] you touch."
    c. For one step claims combining disinfection and cleaning/deodorizing or sanitization and cleaning/deodorizing, qualify the claims by adding "when directions for use for disinfection/sanitization are followed."
    d. Revise all 99.999% and 99.99% kill claims with 99.9% when describing organisms or bacteria associated with disinfection, such as *Salmonella enterica*, *Streptococcus pyogenes*, *Staphylococcus aureus*, MRSA, *Listeria monocytogenes*, and general bacterial claims.
    e. Remove "Respiratory Viruses" and "Viruses that cause respiratory illness" from the claim "Kills 99.9% of [Viruses†] [Respiratory Viruses‡] [Viruses that cause respiratory illness‡] {select from list of virus[es]} ..."
    f. Revise "Kills 99.9[9]% of Flu Viruses…" with "Kills 99.9% of Flu viruses…" Efficacy data demonstrated a 3.25 log reduction which does not support a 99.99% (4-log) reduction claim.
    g. For cold and/or flu claims, revise the claims as follows: "Kills viruses that may cause cold and flu: Respiratory Syncytial virus [RSV], Human Coronvirus and Influenza A virus, Influenza A virus" or "kills 99.9% of virus that may cause the flu: Influenza A virus."
    h. The claim "[Rapidly] [Kills] [Eliminates] 99.9% of [germs] bacteria [**]in [just] [only] 10 sec[onds] [in (One-Step) (1-Step)]" should be qualified to indicate for non-food contact surface sanitizer use. Remove the claim for germs.

16. On page 16 of the proposed label, please remove/revise the following:
    a. Remove the claim "This product kills all common household germs to help prevent the cross contamination of germs in high traffic areas and children's items".
    b. Revise all claims associated with cross-contamination with "Reduce the cross

contamination of…" and remove brackets from "on hard, nonporous surfaces" in these claims.

c. Clarify the claim "[Each wipe is] [Xx] [stronger] [thicker] for [heavy duty] [deep] cleaning [and disinfecting]". Comparative statements are limited to within a company's own products.
d. Remove the claim "[Kills] [disinfects] [eliminates] [99.9(9)(9)% of] Escherichia coli (E. coli) [in 60 sec(onds)] [in 1 min(ute)]". This claim was not substantiated by efficacy data for disinfection.
e. Revise the claim "Kills bacteria -and/or- viruses that cause respiratory infection: Klebsiella pneumoniae [(cause of pneumoniae)] -and/or Respiratory Syncytial virus [RSV] (cause of respiratory infections in infants) -and/or- Human coronavirus [(the virus that causes the cold -or- the cold virus [‡])] -and/or- Influenza A virus [the virus that causes the flu -or- flu virus [‡]]" by qualifying "viruses", remove "that cause respiratory infection", remove "Klebsiella pneumoniae [(cause of pneumoniae)]", and remove "Respiratory Syncytial virus [RSV] (cause of respiratory infections in infants)". Statements that imply or suggest that the product can or will prevent or control disease or offer health protection are not acceptable. Refer to the Chapter 12 of the Label Review Manual for more information: https://www.epa.gov/sites/production/files/2017-10/documents/chap-12-nov-2013.pdf

   For cold and/or flu claims, revise the claims as follows: "Kills viruses that may cause cold and flu: Respiratory Syncytial virus [RSV], Human Coronavirus, and Influenza A virus."

17. Please remove/revise the section USE SITES/SURFACES as follows:
    a. The heading for "USE SITES/SURFACES" should specify for use on hard, non-porous surfaces.
    b. Remove any use surfaces that are designed for direct food contact, including but not limited to cutting boards, any washable food contact surfaces, baby bottles, water bottles, coffee mugs, and coffee pots (unless the exterior surface is specified for bottles), dishes, drain boards, glassware, pots and pans, sippy cups, ice cream scoops, cutlery, baby feeding spoon, food preparation surfaces, cutting implements, cutting tools, and eating utensils. Refer to label recommendation #6.
    c. Remove all use surfaces that are clearly not hard, non-porous surfaces, such as laundries and lunch bags.
    d. For urinals and toilets, specify that for use on the exterior surface of these objects. Remove toilet bowl surfaces.

18. The disclaimer that the product is not to be used as a terminal sterilant/high-disinfectant is required to be added to the label.

19. The proposed label claims that the product, JigSAW (EPA Reg. File No. 84150-R), qualifies for emerging viral pathogens claims are not acceptable. Addition of these claims requires receipt of a terms of registration letter to add Emerging Pathogen Claims that includes the appropriate request to make emerging viral pathogen claims, a description of how the product meets the eligibility criteria, the identification of all viruses from the product label that support the emerging viral pathogen claims, and any other appropriate regulatory documents. In addition, a data matrix should be provided that lists the supporting studies for each virus for which emerging pathogens claims are being made.
    Until the Terms of Registration letter is received, please remove the Claims Against Emerging Viral Pathogens from page 4 of the proposed label. Please refer to the following website for more information:
    https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-antimicrobial-pesticides